

K091374

MAY 26 2009

Attachment B
Summary of Safety and Effectiveness
Prepared in accordance with 21 CFR Part 807.92(c).



GE Healthcare

GE Medical Systems (China) Co., Ltd
No. 19 Changjiang Road, National Hi-Tech Development Zone
Wuxi, Jiangsu Province, CHINA 214028

Section a):

1. **Submitter:** GE Medical Systems (China) Co., Ltd.
No. 19 Changjiang Road, National Hi-Tech Development Zone, Wuxi, Jiangsu Province,
CHINA 214028

Contact Person: Yalan Wu,
Manager, Safety and Regulatory
Telephone: 86-510-85278652; Fax: 86-510-85227347

Date Prepared: April 20, 2009
2. **Device Name:** GE LOGIQ i/e, Vivid e Ultrasound
Ultrasonic Pulsed Echo Imaging System, 21 CFR 892.1560, 90-IYO
Ultrasonic Pulsed Doppler Imaging System, 21 CFR 892.1550, 90-IYN
Diagnostic Ultrasonic Transducer, 21 CFR 892.1570, 90-ITX
3. **Marketed Device:** GE LOGIQ-i/e & Vivid-e Compact Ultrasound, 510(k) No: K072797
(90-IYO/IYN/ITX) A device currently in commercial distribution.

GE Venue 40 Compact Ultrasound, 510(k) No: K091164
(90-IYO/IYN/ITX) A device currently cleared and starting to commercial distribution.
4. **Device Description:** The GE Compact Ultrasound is a very compact and portable diagnostic ultrasound system having three variations: LOGIQ i, LOGIQ e and Vivid e, each with options and features suited for its market niche. It has an integrated keyboard, LCD display and several interchangeable electronic-array transducers with an approximate size of 34 cm wide, 29 cm deep and 6 cm high in transport configuration and provides digital acquisition, processing and display capability. The user interface includes a computer keyboard, an intuitive layout of specialized controls, color GUI display and Doppler audio.
5. **Indications for Use:** The subject modified device is a general purpose ultrasound system intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include: Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ (breast, testes, thyroid); Neonatal and Adult Cephalic; Cardiac (adult & pediatric); Peripheral Vascular; Intra-operative (abdominal, thoracic and PV), Musculo-skeletal Conventional & Superficial, Transrectal and Transvaginal, and Thoracic/Pleural for motion/sliding and fluid detection.
6. **Comparison with Predicate Device:** The modified device is of a comparable type and substantially equivalent to the current GE LOGIQ e and Venue 40 with overall performance in a small and compact package. It has the same overall characteristics, key safety and effectiveness features, physical design, general overall construction, and materials. And all technological characteristics and safety and effectiveness features are equivalent.

Section b):

1. **Non-clinical Tests:** The device has been evaluated for acoustic output, biocompatibility, cleaning and disinfection effectiveness, electromagnetic compatibility, as well as thermal, electrical and mechanical safety, and has been found to conform with applicable medical device safety standards.
2. **Clinical Tests:** None required.
3. **Conclusion:** Intended uses and other key features are consistent with traditional clinical practice, FDA guidelines, and established methods of patient examination. The design and development process of the manufacturer conforms with 21 CFR 820, ISO 9001:2000 and ISO 13485 quality systems. The device conforms to applicable medical device safety standards and compliance is verified through independent evaluation with ongoing factory surveillance. Diagnostic ultrasound has accumulated a long history of safe and effective performance. Therefore, it is the opinion of GE Healthcare that the GE LOGIQ i/e Vivid e Ultrasound imaging device is substantially equivalent with respect to safety and effectiveness to devices currently cleared for market.



MAY 26 2009

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

GE Medical Systems, Ultrasound and Primary Care Diagnostics, LLC
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K091374

Trade/Device Name: GE LOGIQ i/e & Vivid e Compact Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: May 8, 2009
Received: May 11, 2009

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the GE LOGIQ i/e & Vivid e Compact Ultrasound System, as described in your premarket notification:

Transducer Model Number

4C-RS
8C-RS
E8C-RS
8L-RS

9L-RS
12L-RS
16L-RS
i12L-RS

i/t739-RS
3S-RS
6S-RS
P2D

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (240) 276-3666.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Indications for Use

510(k) Number (if known): K091374

Device Name: GE LOGIQ i/e & Vivid e Compact Ultrasound

Indications For Use:

The LOGIQ i/e & Vivid e is a general purpose ultrasound system intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include: Fetal/OB; Abdominal (GYN & Urology); Pediatric; Small Organ (breast, testes, thyroid); Neonatal and Adult Cephalic; Cardiac (adult & pediatric); Peripheral Vascular; Intra-operative (abdominal, thoracic and PV), Musculo-skeletal Conventional & Superficial, Transrectal and Transvaginal, and Thoracic/Pleural for motion/sliding and fluid detection.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number K091374

Page 1 of 1

Diagnostic Ultrasound Indications for Use Form

GE Compact Ultrasound System

LOGIQ *i*, LOGIQ *e*, Vivid *e*

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse*	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P	P	
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ ^[2]	P	P	P		P		P	P	P	P	
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac ^[3]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular	P	P	P	P	P		P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P		P	P	P	P	
Musculo-skeletal Superficial	N	N	N		N		N	N	N	N	
Thoracic/Pleural (specify) ^[4]	N	N	N	N	N	N	N	N	N	N	
Other ^[5]	P	P	P	P	P	P	P	P	P	P	
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal	P	P	P		P		P	P	P		
Transvaginal	P	P	P		P		P	P	P		
Transurethral											
Intraoperative	P	P	P		P		P	P	P	P	
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Notes: [1] Abdominal includes GYN and Urological
[2] Small organ includes breast, testes, thyroid.
[3] Cardiac is Adult and Pediatric.
[4] For detection of fluid and pleural motion/sliding;
[5] Other use includes Urology/Prostate
[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD
[*] Coded Pulse is for digitally encoded harmonics.

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Division of Reproductive, Abdominal and
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510(k) Number 15091374

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number 15091374

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE Compact Ultrasound with 4C-RS Transducer
 LOGIQ i, LOGIQ e, Vivid e

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse*	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P		P		P	P	P	P	
Abdominal ^[1]	P	P	P		P		P	P	P	P	
Pediatric	P	P	P		P		P	P	P	P	
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural (specify) ^[4]	N	N	N		N		N	N	N	N	
Other ^[5]	P	P	P		P		P	P	P	P	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Notes: [1] Abdominal includes GYN and Urological
 [2] Small organ includes breast, testes, thyroid.
 [3] Cardiac is Adult and Pediatric.
 [4] For detection of fluid and pleural motion/sliding;
 [5] Other use includes Urology/Prostate
 [*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.
 [*] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal and
 Radiological Devices

510(k) Number 5091374

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE Compact Ultrasound with 8C-RS Transducer
LOGIQ *i*, LOGIQ *e*, Vivid *e*

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	P	P	P		P		P	P	P		
Pediatric	P	P	P		P		P	P	P		
Small Organ (specify)	P	P	P		P		P	P	P		
Neonatal Cephalic	P	P	P		P		P	P	P		
Adult Cephalic											
Cardiac ^[3]	P	P	P		P		P	P	P		
Peripheral Vascular	P	P	P		P		P	P	P		
Musculo-skeletal Conventional	P	P	P		P		P	P	P		
Musculo-skeletal Superficial											
Thoracic/Pleural (specify) ^[4]	N	N	N		N		N	N	N		
Other ^[5]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN and Urological

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] For detection of fluid and pleural motion/sliding;

[5] Other use includes Urology/Prostate

[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

[†] Coded Pulse is for digitally encoded harmonics.

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Division of Reproductive, Abdominal and
Radiological Devices

Prescription User (Per 21 CFR 801.109)

510(k) Number 16091374

Diagnostic Ultrasound Indications for Use Form
GE Compact Ultrasound with E8C-RS Transducer
LOGIQ i, LOGIQ e, Vivid e

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/ Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	
Ophthalmic											
Fetal / Obstetrics	P	P	P		P		P	P	P		
Abdominal ^[1]	P	P	P		P		P	P	P		
Pediatric											
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural (specify) ^[4]											
Other ^[5]	P	P	P		P		P	P	P		
Exam Type, Means of Access											
Transesophageal											
Transrectal	P	P	P		P		P	P	P		
Transvaginal	P	P	P		P		P	P	P		
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN and Urological

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] For detection of fluid and pleural motion/sliding;

[5] Other use includes Urology/Prostate

[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

[†] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

5091374

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE Compact Ultrasound with 8L-RS Transducer
 LOGIQ i, LOGIQ e, Vivid e

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes*	Harmonic Imaging	Coded Pulse†	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	P	P	P		P		P	P	P	P	
Pediatric	P	P	P		P		P	P	P	P	
Small Organ (specify) ^[2]	P	P	P		P		P	P	P	P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]	P	P	P		P		P	P	P		
Peripheral Vascular	P	P	P		P		P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P		P	P	P		
Musculo-skeletal Superficial											
Thoracic/Pleural (specify) ^[4]											
Other ^[5]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify) ^[5]	P	P	P		P		P	P	P		
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

- Notes: [1] Abdominal includes GYN and Urological
 [2] Small organ includes breast, testes, thyroid.
 [3] Cardiac is Adult and Pediatric.
 [4] For detection of fluid and pleural motion/sliding;
 [5] Other use includes Urology/Prostate
 [*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.
 [†] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal and
 Radiological Devices

Prescription User (Per 21 CFR 801.109)

510(k) Number

6091374

Diagnostic Ultrasound Indications for Use Form
GE Compact Ultrasound with 9L-RS Transducer
 LOGIQ i, LOGIQ e, Vivid e

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse*	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	P	P	P		P		P	P	P	P	
Pediatric	P	P	P		P		P	P	P	P	
Small Organ (specify) ^[2]	P	P	P		P		P	P	P	P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]											
Peripheral Vascular	P	P	P		P		P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P		P	P	P	P	
Musculo-skeletal Superficial											
Thoracic/Pleural (specify) ^[4]											
Other ^[5]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify) ^[5]	P	P	P		P		P	P	P	P	
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN and Urological

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] For detection of fluid and pleural motion/sliding;

[5] Other use includes Urology/Prostate

[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

[†] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal and
 Radiological Devices

510(k) Number 15091374

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE Compact Ultrasound with 12L-RS Transducer
 LOGIQ i, LOGIQ e, Vivid e

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse [†]	
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric	P	P	P		P		P	P	P	P	
Small Organ ^[2]	P	P	P		P		P	P	P	P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	P	P	P		P		P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P		P	P	P	P	
Musculo-skeletal Superficial	N	N	N		N		N	N	N	N	
Thoracic/Pleural (specify) ^[4]	N	N	N		N		N	N	N	N	
Other (specify) ^[5]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[5] (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN and Urological

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] For detection of fluid and pleural motion/sliding;

[5] Other use includes Urology/Prostate

[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

[†] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal and
 Radiological Devices

510(k) Number

15091374

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE Compact Ultrasound with 16L-RS Transducer

LOGIQ i, LOGIQ e, Vivid e

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse*	
Ophthalmic											
Fetal / Obstetrics											
Abdominal											
Pediatric	E	E	E		E		E	E	E	E	
Small Organ ^[2]	E	E	E		E		E	E	E	E	
Neonatal Cephalic											
Adult Cephalic											
Cardiac											
Peripheral Vascular	E	E	E		E		E	E	E	E	
Musculo-skeletal Conventional	E	E	E		E		E	E	E	E	
Musculo-skeletal Superficial	N	N	N		N		N	N	N	N	
Thoracic/Pleural (specify) ^[4]											
Other (specify) ^[5]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative ^[3] (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN and Urological

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] For detection of fluid and pleural motion/sliding;

[5] Other use includes Urology/Prostate

[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

[†] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

6091374

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE Compact Ultrasound with i12L-RS Transducer
 LOGIQ i, LOGIQ e, Vivid e

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse*	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	P	P	P		P		P	P	P	P	
Pediatric	P	P	P		P		P	P	P	P	
Small Organ (specify) ^[2]	P	P	P		P		P	P	P	P	
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]	P	P	P		P		P	P	P		
Peripheral Vascular	P	P	P		P		P	P	P	P	
Musculo-skeletal Conventional	P	P	P		P		P	P	P		
Musculo-skeletal Superficial	N	N	N		N		N	N	N		
Thoracic/Pleural (specify) ^[4]											
Other ^[5]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify) ^[5]	P	P	P		P		P	P	P		
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN and Urological

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] For detection of fluid and pleural motion/sliding;

[5] Other use includes Urology/Prostate

[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

[*] Coded Pulse is for digitally encoded harmonics.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)

Division of Reproductive, Abdominal and
 Radiological Devices

510(k) Number

15091374

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE Compact Ultrasound with i/t739-RS Transducers
 LOGIQ i, LOGIQ e, Vivid e

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	P	P	P		P		P	P	P		
Pediatric	P	P	P		P		P	P	P		
Small Organ (specify) ^[2]	P	P	P		P		P	P	P		
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]	P	P	P		P		P	P	P		
Peripheral Vascular	P	P	P		P		P	P	P		
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural (specify) ^[4]											
Other ^[4]											
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify) ^[5]	P	P	P		P		P	P	P		
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN and Urological

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] For detection of fluid and pleural motion/sliding;

[5] Other use includes Urology/Prostate

[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

[†] Coded Pulse is for digitally encoded harmonics.

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Division of Reproductive, Abdominal and
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510(k) Number

K091374

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE Compact Ultrasound with 3S-RS Transducer
 LOGIQ i, LOGIQ e, Vivid e

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application Anatomy/Region of Interest	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse*	Other
Ophthalmic											
Fetal / Obstetrics	P	P	P	P	P	P	P	P	P	P	
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ (specify)											
Neonatal Cephalic											
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac ^[3]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural (specify) ^[4]	N	N	N	N	N	N	N	N	N	N	
Other ^[5]	P	P	P	P	P	P	P	P	P	P	
Exam Type, Means of Access											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify)											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN and Urological

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] For detection of fluid and pleural motion/sliding;

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[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Reproductive, Abdominal and
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510(k) Number

15091374

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE Compact Ultrasound with 6S-RS Transducer
LOGIQ *i*, LOGIQ *e*, Vivid *e*

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse*	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]	P	P	P	P	P	P	P	P	P	P	
Pediatric	P	P	P	P	P	P	P	P	P	P	
Small Organ (specify) ^[2]											
Neonatal Cephalic	P	P	P	P	P	P	P	P	P	P	
Adult Cephalic	P	P	P	P	P	P	P	P	P	P	
Cardiac ^[3]	P	P	P	P	P	P	P	P	P	P	
Peripheral Vascular											
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural (specify) ^[4]											
Other ^[5]	P	P	P	P	P	P	P	P	P	P	
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify) ^[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN and Urological

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] For detection of fluid and pleural motion/sliding;

[5] Other use includes Urology/Prostate

[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

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Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

K091314

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use Form
GE Compact Ultrasound with P2D Transducer
LOGIQ *i*, LOGIQ *e*, Vivid *e*

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application <i>Anatomy/Region of Interest</i>	Mode of Operation										
	B	M	PW Doppler	CW Doppler	Color Doppler	Color M Doppler	Power Doppler	Combined Modes	Harmonic Imaging	Coded Pulse*	Other
Ophthalmic											
Fetal / Obstetrics											
Abdominal ^[1]											
Pediatric											
Small Organ (specify) ^[2]											
Neonatal Cephalic											
Adult Cephalic											
Cardiac ^[3]				P							
Peripheral Vascular				P							
Musculo-skeletal Conventional											
Musculo-skeletal Superficial											
Thoracic/Pleural (specify) ^[4]											
Other ^[5]											
<i>Exam Type, Means of Access</i>											
Transesophageal											
Transrectal											
Transvaginal											
Transurethral											
Intraoperative (specify) ^[5]											
Intraoperative Neurological											
Intravascular											
Laparoscopic											

N = new indication; P = previously cleared by FDA; E = added under Appendix E

Notes: [1] Abdominal includes GYN and Urological

[2] Small organ includes breast, testes, thyroid.

[3] Cardiac is Adult and Pediatric.

[4] For detection of fluid and pleural motion/sliding;

[5] Other use includes Urology/Prostate

[*] Combined modes are B/M, B/PWD, B/Color/PWD, B/Power/PWD.

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Division of Reproductive, Abdominal and
Radiological Devices

510(k) Number

6091374

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